

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS AG,
NOVARTIS PHARMA AG, NOVARTIS
INTERNATIONAL PHARMACEUTICAL
LTD. and LTS LOHMANN THERAPIE-
SYSTEME AG,

Plaintiffs,

v.

ALVOGEN PINE BROOK, INC. and
ALVOGEN GROUP, INC.,

Defendants.

C.A. No. 1:13-cv-00052-RGA

**ALVOGEN PINE BROOK, INC. AND
ALVOGEN GROUP, INC.'S ANSWER AND COUNTERCLAIMS**

Defendants Alvogen Pine Brook, Inc. and Alvogen Group, Inc. (collectively "Alvogen") hereby respond to the corresponding paragraphs of the Complaint of Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively "Plaintiffs") by their undersigned attorneys as follows:

NATURE OF THE ACTION

1. The Complaint speaks for itself and no answer by Alvogen is required.

PARTIES

2. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint and, therefore, denies the same.

3. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 3 of the Complaint and, therefore, denies the same.

4. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint and, therefore, denies the same.

5. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 5 of the Complaint and, therefore, denies the same.

6. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 6 of the Complaint and, therefore, denies the same.

7. Admitted that Alvogen Pine Brook, Inc. is incorporated in Delaware and has its principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, NJ, 07058.

8. Admitted that Alvogen Group, Inc. is incorporated in Delaware and has its principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, NJ, 07058.

9. Admitted.

10. Denied.

11. Paragraph 11 of the Complaint contains a description to which no answer is required.

JURISDICTION AND VENUE

12. Admitted.

13. Admitted that Alvogen Group, Inc. is incorporated in Delaware and that Alvogen Group, Inc. consents to personal jurisdiction for the limited purposes of this action only. The terms “affiliates” and “agents” call for a legal conclusion to which no answer is required. Alvogen Group, Inc. denies the remaining allegations in Paragraph 13 of the Complaint.

14. Admitted that Alvogen Pine Brook, Inc. is incorporated in Delaware and that Alvogen Pine Brook, Inc. consents to personal jurisdiction for the limited purposes of this action only. Alvogen Pine Brook, Inc. denies the remaining allegations in Paragraph 14 of the

Complaint.

15. Paragraph 15 contains a legal conclusion to which no answer is required. To the extent an answer is required, Alvogen consents to personal jurisdiction for the limited purposes of this action only.

16. Paragraph 16 contains a legal conclusion to which no answer is required. To the extent an answer is required, Alvogen does not contest venue in this judicial district for the limited purposes of this action only.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

17. Denied, except to state that New Drug Application (“NDA”) No. 22-083 was approved by the Food and Drug Administration (“FDA”) on July 6, 2007 for the manufacture and sale of rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr. Alvogen further states that NDA No. 22-083 was approved by the FDA on August 31, 2012 for the manufacture and sale of rivastigmine transdermal system, 13.3 mg/24 hr. Alvogen further states the FDA approved Exelon[®] Patch, rivastigmine transdermal system, for the treatment of mild to moderate dementia of the Alzheimer’s type and mild to moderate dementia associated with Parkinsons’s Disease. Alvogen is without sufficient knowledge to admit or deny the remainder of the allegations in Paragraph 17 of the Complaint and, therefore, denies the same.

18. Admitted, on information and belief.

19. Admitted that the ‘023 patent on its face states an issue date of November 13, 2001 and identifies the assignees as Novartis AG and LTS Lohmann Therapie-Systeme GmbH. Alvogen denies that the ‘023 patent was duly and legally issued. Alvogen is without sufficient knowledge to admit or deny the remainder of the allegations in Paragraph 19 of the Complaint and, therefore, denies the same.

20. Admitted that Exhibit A appears to be a true and correct copy of the '023 patent. The claims of the '023 patent speak for themselves and no answer is required. The remainder of the allegations in Paragraph 20 of the Complaint set forth legal conclusions and characterizations to which no answer is required.

21. Admitted that the '031 patent on its face states an issue date of January 1, 2002 and identifies the assignees as Novartis AG and LTS Lohmann Therapie-Systeme GmbH Co. KG. Alvogen denies that the '031 patent was duly and legally issued. Alvogen is without sufficient knowledge to admit or deny the remainder of the allegations in Paragraph 21 of the Complaint and, therefore, denies the same.

22. Admitted that Exhibit B appears to be a true and correct copy of the '031 patent. The claims of the '031 patent speak for themselves and no answer is required. The remainder of the allegations in Paragraph 22 of the Complaint set forth legal conclusions and characterizations to which no answer is required.

23. Alvogen is without sufficient knowledge to admit or deny the allegations in Paragraph 23 of the Complaint and, therefore, denies the same.

24. Admitted that Alvogen Pine Brook, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 204403 to the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of rivastigmine transdermal system extended release film, 4.6 mg/24 hr and 9.5 mg/24 hr ("Alvogen's ANDA Products"), which includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that such manufacture, use or sale of Alvogen's ANDA Products will not infringe any valid or enforceable claims of the '023 and '031 patents. Alvogen denies the remaining allegations in Paragraph 24 of the Complaint.

25. Admitted that Alvogen Pine Brook, Inc. submitted ANDA No. 204403 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '023 and '031 patents contending that the claims of the '023 and '031 patents will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of the Alvogen's ANDA Products, and/or that the claims of these patents are invalid and/or unenforceable.

26. Admitted that Alvogen Pine Brook, Inc. submitted ANDA No. 204403 to the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of Alvogen's ANDA Products. Alvogen denies the remaining allegations in Paragraph 26 of the Complaint.

27. Admitted that Alvogen Pine Brook, Inc. submitted ANDA No. 204403 to the FDA and was aware of the '023 and '031 patents at the time of filing ANDA No. 204403 with the FDA. Alvogen denies the remaining allegations in Paragraph 27 of the Complaint.

28. Denied.

29. Denied.

30. Denied.

31. Denied.

32. Admitted that Alvogen Pine Brook, Inc. submitted ANDA No. 204403 to the FDA in order to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Products and that Alvogen Pine Brook, Inc. is seeking FDA approval of Alvogen's ANDA Products. Alvogen denies the remaining allegations in Paragraph 32 of the Complaint.

33. Paragraph 33 contains a legal conclusion to which no answer is required. Alvogen denies the remaining allegations in Paragraph 33 of the Complaint.

PRAYER FOR RELIEF

WHEREFORE, Alvogen denies that Plaintiffs are entitled to the relief requested in the Complaint.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and to its ability to seek and allege any and all defenses not presently known or that are revealed during the course of discovery, Alvogen asserts the following affirmative defenses in response to the Complaint:

First Affirmative Defense

The claims of the '023 and '031 patents are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112 and/or the judicial doctrine barring double-patenting.

Second Affirmative Defense

Alvogen has not infringed, is not infringing and will not infringe, either directly or by contribution or inducement, any valid and enforceable claim of the '023 and '031 patents.

Third Affirmative Defense

The doctrines of prosecution history estoppel, by argument or amendment, preclude any finding of infringement of the '023 and '031 patents.

Fourth Affirmative Defense

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

For its counterclaims against Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-

Systeme AG (collectively “Counterclaim-Defendants”), Alvogen Pine Brook, Inc. and Alvogen Group, Inc. (collectively “Alvogen”) allege upon knowledge with respect to its own acts, and upon information and belief as to other matters, as follows:

The Parties

1. Alvogen Pine Brook, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

2. Alvogen Group, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

3. On information and belief, Novartis Pharmaceuticals Corporation is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

4. On information and belief, Novartis AG is a company organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. On information and belief, Novartis Pharma AG is a company organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. On information and belief, Novartis International Pharmaceuticals Ltd. is a company organized and existing under the laws of Bermuda, with its principal place of business at 131 Front Street, Hamilton HM12, Bermuda.

7. On information and belief, LTS Lohmann Therapie-Systeme AG is a company

organized and existing under the laws of Germany, with its principal place of business at Lohmannstrasse 2, D-56626 Andernach, Germany.

Facts As to All Counterclaims

8. Alvogen repeats and realleges Paragraphs 1-7 of the Counterclaims.

9. The Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

10. Personal jurisdiction over the Counterclaim-Defendants exists because the Counterclaim-Defendants have submitted to the personal jurisdiction of the Court.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because the Counterclaim-Defendants have submitted to the jurisdiction of the Court.

12. On January 4, 2013, Counterclaim-Defendants filed a Complaint alleging, *inter alia*, infringement of United States Patent No. 6,316,023 (“the ‘023 patent”) and United States Patent No. 6,335,031 (“the ‘031 patent”).

13. In their Complaint, Counterclaim-Defendants allege that Alvogen’s submission of Abbreviated New Drug Application (“ANDA”) No. 204403 to the Food and Drug Administration (“FDA”), infringes one or more claims of the ‘023 and ‘031 patents. The submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any claim of the ‘023 patent or the ‘031 patent.

14. In their Complaint, Counterclaim-Defendants allege that Novartis AG and LTS Lohmann Therapie-Systeme AG are the owners of the ‘023 patent. The face of the ‘023 patent states an issue date of November 13, 2001 and identifies the assignees as Novartis AG and LTS Lohmann Therapie Systeme GmbH.

15. In their Complaint, Counterclaim-Defendants allege that Novartis AG and LTS Lohmann Therapie-Systeme AG are the owners of the '031 patent. The face of the '031 patent states an issue date of January 1, 2002 and identifies the assignees as Novartis AG and LTS Lohmann Therapie-Systeme GmbH Co. KG.

16. Actual and justiciable controversies exist between Alvogen and Counterclaim-Defendants relating to the '023 and '031 patents.

Count I: Declaration of Noninfringement of the '023 Patent

17. Alvogen repeats and realleges paragraphs 1-16 of the Counterclaims.

18. The submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any claim of the '023 patent.

19. The commercial manufacture, use, sale, offer for sale or importation of rivastigmine transdermal system extended release film, 4.6 mg/24 hr and 9.5 mg/24 hr ("Alvogen's ANDA Products") does not and will not infringe any claim of the '023 patent.

20. An actual and justiciable controversy exists between Alvogen and Counterclaim-Defendants regarding the noninfringement of the '023 patent.

21. Alvogen is entitled to a declaration that the submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any claim of the '023 patent.

22. Alvogen is entitled to a declaration that the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Products does not and will not infringe any claim of the '023 patent.

Count II: Declaration of Invalidity of the '023 Patent

23. Alvogen repeats and realleges paragraphs 1-22 of the Counterclaims.

24. The claims of the '023 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112 and/or the judicial doctrine barring double-patenting.

25. An actual and justiciable controversy exists between Alvogen and Counterclaim-Defendants regarding the validity of the '023 patent.

26. Alvogen is entitled to a declaration that the '023 patent is invalid.

Count III: Declaration of Noninfringement of the '031 Patent

27. Alvogen repeats and realleges paragraphs 1-26 of the Counterclaims.

28. The submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any claim of the '031 patent.

29. The commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Products does not and will not infringe any claim of the '031 patent.

30. An actual and justiciable controversy exists between Alvogen and Counterclaim-Defendants regarding the noninfringement of the '031 patent.

31. Alvogen is entitled to a declaration that the submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any claim of the '031 patent.

32. Alvogen is entitled to a declaration that the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Products does not and will not infringe any claim of the '031 patent.

Count IV: Declaration of Invalidity of the '031 Patent

33. Alvogen repeats and realleges paragraphs 1-32 of the Counterclaims.

34. The claims of the '031 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112 and/or the

judicial doctrine barring double-patenting.

35. An actual and justiciable controversy exists between Alvogen and Counterclaim-Defendants regarding the validity of the '031 patent.

36. Alvogen is entitled to a declaration that the '031 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Alvogen respectfully requests this Court to enter judgment for Alvogen and against Counterclaim-Defendants, and decree:

- A. That the Complaint be dismissed with prejudice, and that Counterclaim-Defendants take nothing by their Complaint;
- B. That any valid claim of the '023 and '031 patents are not infringed by Alvogen;
- C. That the submission of ANDA No. 204403 by Alvogen Pine Brook, Inc. does not infringe any valid claim of the '023 and '031 patents;
- D. That the commercial manufacture, use, sale, offer for sale or importation of Alvogen's ANDA Products does not and will not infringe any valid claim of the '023 or '031 patents.
- E. That the claims of the '023 and '031 patents are invalid;
- F. That this is an exceptional case under 35 U.S.C. § 285;
- G. That Alvogen be awarded its costs and attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;
- H. That the Counterclaim-Defendants, their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with the counterclaim-defendants, be preliminarily and permanently enjoined from using the '023 and '031 patents to

block, hamper, hinder or obstruct FDA approval of the products described in ANDA

No. 204403; and

I. That Alvogen be awarded such other and further relief as the Court deems just and proper.

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